



# GENERAL ASSEMBLY

## COMMONWEALTH OF KENTUCKY

### 2010 REGULAR SESSION

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SENATE BILL NO. 18

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WEDNESDAY, FEBRUARY 10, 2010

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The following bill was reported to the House from the Senate and ordered to be printed.

RECEIVED AND FILED  
DATE 3/24/10 12:25 pm

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TREY GRAYSON  
SECRETARY OF STATE  
COMMONWEALTH OF KENTUCKY  
BY [Signature]

AN ACT relating to health care services provided in clinical trials for the treatment of cancer.

*Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

➔SECTION 1. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section, unless the context requires otherwise:

(a) "Cancer clinical trial" means a clinical trial that:

1. Is approved by:

a. The National Institutes of Health, or any institutional review board recognized by the National Institutes of Health;

b. The United States Food and Drug Administration;

c. The United States Department of Defense; or

d. The United States Veterans Administration; and

2. Does one (1) of the following:

a. Tests how to administer a health care service, item, or drug for the treatment of cancer;

b. Tests responses to a health care service, item, or drug for the treatment of cancer;

c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer; or

d. Studies new uses of health care services, items, or drugs for the treatment of cancer.

(b) "Routine patient healthcare costs" means all healthcare services, items, and drugs for the treatment of cancer except for the following:

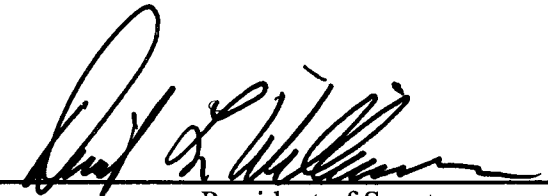
1. The healthcare service, item, or investigational drug that is the subject of the cancer clinical trial;

- 1           2. Any treatment modality outside the usual and customary standard of  
2           care required to administer or support the healthcare service, item, or  
3           investigational drug that is the subject of the cancer clinical trial;
- 4           3. Any healthcare service, item, or drug provided solely to satisfy data  
5           collection and analysis needs that are not used in the direct clinical  
6           management of the patient;
- 7           4. An investigational drug or device that has not been approved for  
8           market by the United States Food and Drug Administration;
- 9           5. Transportation, lodging, food, or other expenses for the patient or a  
10          family member or companion of the patient that are associated with  
11          travel to or from a facility providing the cancer clinical trial;
- 12          6. Any services, items, or drugs provided by the cancer clinical trial  
13          sponsors free of charge for any new patient; or
- 14          7. Any services, items, or drugs that are eligible for reimbursement by a  
15          person other than the insurer, including the sponsor of the clinical  
16          trial.
- 17   (2) A health benefit plan shall not exclude coverage for routine patient healthcare  
18   costs that are incurred in the course of a cancer clinical trial if the health benefit  
19   plan would provide coverage for the routine patient healthcare costs had they not  
20   been incurred in a cancer clinical trial.
- 21   (3) The coverage that may not be excluded under this section shall be subject to all  
22   terms, conditions, restrictions, exclusions, and limitations that apply to any other  
23   coverage under the policy, plan, or contract, including the treatment under the  
24   policy, plan, or contract of services performed by participating and  
25   nonparticipating providers.
- 26   (4) (a) Nothing in this section requires a policy, plan, or contract to offer cancer  
27   clinical trial services by a participating provider.

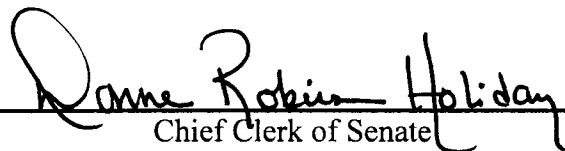
1       **(b) Nothing in this section prohibits a policy, plan, or contract from offering**  
2       **cancer clinical trial services by a participating provider.**

3       **(c) Nothing in this section requires services that are performed in a cancer**  
4       **clinical trial by a nonparticipating provider of a policy, plan, or contract to**  
5       **be reimbursed at the same rate as those performed by a participating**  
6       **provider of the policy, plan, or contract.**

7       **(5) Nothing in this section shall be construed as imposing a new health benefit**  
8       **mandate.**

  
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President of Senate

  
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Speaker-House of Representatives

Attest:   
\_\_\_\_\_  
Chief Clerk of Senate

Approved   
\_\_\_\_\_  
Governor

Date March 24, 2010